

This summary statement complies with 21CFR, section 807.92(c).  
Date summary prepared: 19 March 2004

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS MRV software package. Pie Medical Imaging is located at:

**JUL 27 2004**

**Pie Medical Imaging BV  
Becanusstraat 13 D 01  
6216 BX Maastricht  
The Netherlands  
Phone +31.43.3281328  
Fax +31.42.3281329  
Email: carla.devries@pie.nl**

The contact person is: Ms. Carla de Vries, Quality Assurance Officer

The trade name is: CAAS MRV

The common name is: Magnetic Resonance Ventricular analysis software

The classification name is: Image Processing System (LLZ), CFR 892.2050.

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS MRV software package is substantially equivalent to the quantitative analysis software package MRI-Magnetic resonance Analytical Software System, K994283.

The CAAS MRV is a software tool designed for the functional analysis of the heart based on multi-slice, multi-phase MR images of the heart. Therefore it provides functionality to import and view cine MR datasets of the heart from several vendors from CDROM, hard disk or (optionally) a PACS system. Next, the inner and outer wall of the ventricles can be determined either automatically, semi-automatically or manually. From these contours the ventricular volume, the ejection fraction and other related parameters are determined. Next to the quantification of the ventricular volumes, also the motion of the ventricular wall is quantified. All results of the analysis are available on screen as well as hardcopy, and can be saved.

The intended use of CAAS MRV is to enable the user to:

1. Delineate the inner and outer wall of the ventricles automatically or semi-automatically, as well as the papillary muscles, on MRI images
2. Derive from these contours the global and regional functional parameters like Ejection Fraction, Stroke Volume, Wall Movement etc.

The CAAS MRV has been designed to be used in everyday clinical practice to support clinical diagnoses, as well as for research purposes like clinical research trials.

The CAAS MRV is substantially equivalent to the predicate device mentioned in this summary by using the same technological characteristics and intended use.

The CAAS MRV is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 27 2004

Ms. Carla de Vries  
Quality Assurance Officer  
Pie Medical Imaging bv  
Becanusstraat 13D  
6216 BX Maastricht  
THE NETHERLANDS

Re: K041682  
Trade/Device Name: CAAS MRV  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving  
and communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: June 14, 2004  
Received: June 21, 2004

Dear Ms. de Vries:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

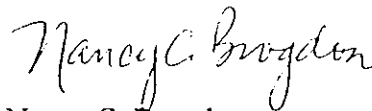
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## 510(k) Notification - CAAS MRV

## INDICATION FOR USE STATEMENT

page 1 of 1

510(k) number (if known): K041682

Device Name: CAAS MRV \_\_\_\_\_

## Indications For Use:

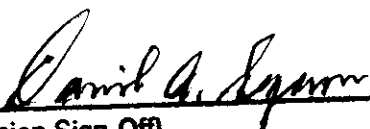
The CAAS MRV has been designed for quantitative functional analysis of the left and right ventricle of the heart based on multi-slice, multi-phase cine MRI images. Specifically, it enables the user to:

1. Delineate automatically or semi-automatically the inner and outer wall of the ventricles, as well as the papillary muscles, on the MRI images
2. Derive from these contours the global and regional functional parameters like Ejection Fraction, Stroke Volume, Wall Movement etc.

The CAAS MRV has been designed to be used in everyday clinical practice, as well as for research purposes like clinical research trials.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041682

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_